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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,144	09/26/2003	Lawrence Tamarkin	01994-0027 (13664.105037)	8073

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EXAMINER	
ANGELL, JON E	

ART UNIT	PAPER NUMBER
1635	

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01/20/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/672,144	TAMARKIN ET AL.	
	Examiner	Art Unit	
	J. E. ANGELL	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Action is in response to the communication filed on 10/19/2009.

Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claims 27-35 are currently pending and are examined herein.

Claim Objections

1. Claims 28, 30, 31, 34 objected to because of the following informalities:

2. Claims 28, 30, 34 contain biological factors which could be made more clear. For instance, the claims include "sense", "antisense", "cancer", and "cell specific antigens" as different biological factors. Applicants are asked to consider amending the claims to make these elements more clear. Specifically: "sense" by itself does not make sense, Applicants are asked to consider changing "sense" to "a polynucleotide sequence that encodes a biologically active factor"; "antisense" by itself is not clear, Applicants are asked to consider changing "antisense" to "an antisense oligonucleotide"; and, it is believed that "cancer, cell specific antigen" is a typographical error that should read "cancer cell specific antigen". Furthermore, claim 31 has a typographical error in line 2 where "selectd" should be "selected".

3. Applicants are asked to consider making the suggested changes or similar changes that would obviate the objection. It is noted that the suggested changes should not be taken as an explicit indication that the specification provides sufficient support for the changes. Applicants

should ensure that any amendment to the claims has proper support in the specification and should identify the location where support can be found.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 27 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,740,589 (Moreno, of record).

The instant claims are drawn to:

27. A method for delivery of more than one biologically-active factor comprising administering to a human or animal a composition comprising more than one biologically-active factor and a target molecule admixed with or bound to a colloidal metal; and,

29. A method for the targeted delivery of one or more biologically-active factors, comprising administering to a human or animal a composition comprising two or more biologically-active factors admixed with or bound to colloidal metal wherein at least one of the biologically-active factors is a target molecule capable of binding a receptor on a cell membrane and wherein at least one of the biologically-active factors is released from the composition in vivo.

It is noted that the term “target” molecule is not specifically defined by the specification, but it is clear that the target molecule can be one of the biologically-active factors, as specifically indicated in claim 29. Therefore, given the broadest reasonable interpretation of the claims consistent with the specification "target molecule" is any molecule, including one of the

biologically-active factors, that preferentially "targets" the composition to particular cells, as opposed to all cells in general.

Moreno teaches a method wherein a complex comprising a metal constituent (e.g., aluminum or ruthenium) a bacterial capsular polysaccharide that contains sialic acid and a third constituent of bacterial outer-membrane protein can be administered to a subject for vaccination, prophylaxis or treatment of bacterial infection, such as cerebrospinal meningitis (e.g., see abstract; columns 7-8, etc.). Moreno also specifically teaches that the complex, when administered to mice, resulted in production of antibodies against group B and type 6 meningococcal antigens in the mice (see Example A, columns 15-16). It is noted that in order for the antibodies to be produced, the antigens would necessarily have to be taken up by antigen presenting cells. Therefore, the antigens, which are biologically-active factors, also act as target molecules because the antigens are not taken up by all cells, but rather the antigens are preferentially taken up by (targeted to) the antigen presenting cells. Furthermore, antigens would necessarily be recognized by receptors on antigen presenting cell membranes to facilitate entry into the cell. Therefore, given the broadest reasonable interpretation of the claims, Moreno anticipates the instant claims.

3. Claims 27, 29, 32 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,269,912 (Grafe, of record).

Claims 27 and 29 are described above. Claim 32 further limits claim 29 by indicating that composition comprises an additional biological factor.

Grafe teaches a method wherein a complex comprising an aluminum oxide colloidally dispersed in an aqueous medium and carrying at least one antigen is used as a vaccine (e.g., see column 7, lines 45-55, etc.). Grafe specifically teaches that the Poliomyelitis vaccine contains a trivalent mixture of poliomyelitis antigens (see column 8, lines 9-19). Grafe also teaches that he method successfully produced antigen-specific antibodies in animals (e.g., see Examples II-V, etc.). It is noted that in order for the antibodies to be produced, the antigens would necessarily have to be taken up by antigen presenting cells. Therefore, the antigens, which are biologically-active factors, also act as target molecules because the antigens are not taken up by all cells, but rather the antigens are preferentially taken up by (targeted to) the antigen presenting cells. Furthermore, antigens would necessarily be recognized by receptors on antigen presenting cell membranes to facilitate entry into the cell. Therefore, given the broadest reasonable interpretation of the claims, Grafe anticipates the instant claims.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 27-35 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-21 of U.S. Patent No. 6,274,552. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are broader in scope than the claims of the '552 patent and thus, the instant claims are anticipated by the narrower claims of the '552 patent. In other words, the claims of the '552 patent are species of the broader (genus-type) instant claims, and since genus claims are anticipated by their species, the instant claims are anticipated by '552 claims.

Response to Arguments

6. Applicant's arguments, have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made for the reasons indicated herein.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. E. ANGELL whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 7:00 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tracy Vivlemore can be reached on 571-272-2914. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. ANGELL/
Primary Examiner, Art Unit 1635